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John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements, CFSAN
Washington, DC 20204

RE: IND Requirement for Dietary Supplements that are New or Being Studied as Treatments for Diseases

Dear Mr. Foret:

Ephedra/Gurana and various associated combinations are being studied in obese patients to prove safety and efficacy for food supplements sold to tens of millions of consumers based on small and highly medically screened patients (highly medically screened by the study managers and sponsors to avoid risks and litigation according to sworn depositions).

According to the medical literature and many government, NIH and other related opinions, obesity is a disease. Use of dietary supplements to treat diseases violates the FDCA as amended by DSHEA. Such studies include those by Boozer et al. One ephedra marketer even claims its product can treat cardiac arrhythmias.

There is nothing dietary about ephedra alkaloids, just as there is nothing dietary about related stimulants (e.g., coca, marijuana, opium, mescaline, psilocybin, digitalis, etc). One of the ephedra alkaloids in ephedra is cathine or norpseudoephedrine, a Schedule IV controlled substance.

At least one investigator (Dr. Frank Greenway) is purchasing ephedrine and caffeine separately, and compounding them as a new drug in his research to support ephedra/gurana dietary supplements in treating the disease obesity. Erroneously, Dr. Greenway believes that the ephedrine/caffeine ban from the early 1980s has been rescinded.

Ephedra marketers are basing their products virtually entirely on published research, over sworn declaration objections of the authors, regarding the patented prescription drug approved and marketed in Denmark by DAK/Nycomed.

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The ephedra industry testified about the use of ephedra in dietary supplements before Representative Dan Burton's hearing March 2001, stating either that ephedra is too dangerous to be sold as a dietary supplement or that it needs more research before is food supplement use can be endorsed. Either way, DSHEA is violated again.

Seemingly misinformed by the study managers (who failed to share with FDA the protocol or any particulars about the planned drug study), comments and July 1997 letters from FDA's Dr. Solomon Sobel and Ms. Enid Galliers to a Vanderbilt University clinical researcher and to an ephedra marketer were used and are being used to eliminate the regulatory need for an IND for new drug and/or new dietary supplement clinical research. Dr. Sobel added that his office has no jurisdiction over dietary supplements (even when explored as treatments of obesity, which is most definitely a responsibility of his office).

Notably, the study by Boozer et al published in the International Journal of Obesity (using placebo pills adulterated with ephedrine and caffeine) reported a 23% withdrawal from the treatment group necessitated by hypertension, chest pain, palpitations and irritability (no such withdrawals occurred in the 'placebo' group, which was in actuality a group taking a small dose of ephedrine/caffeine). The physician overseeing this study has testified that he is very concerned about the ramification of this finding when extrapolated to millions of unscreened used of uncontrolled ephedra/gurana.

A notable death from one of these illicit drug studies will produce significant controversy about clinical research in the United States and FDA's diligence, which will likely rekindle and trump the debacle last year at Johns Hopkins University.

In addition, reminiscent of the fen/phen debacle, at least one website is promoting the use of phentermine and serotonin, ignoring the cardiac vegetations produced by dietary serotonin long known in the scientific literature and fenfluramine/dexfenfluramine-induced cardiac valve disease (http://elm.forest.net/pragmatic/ProdDesc/Interview_Rothman.lasso, http://elm.forest.net/pragmatic/Articles/List_of_All_Articles.lasso, http://www.fatnews.com). Owner of this website actively promotes via his book reports, which are heavily relied upon by the ephedra food supplement marketers, the illegal use of the unapproved drug ephedrine/caffeine for obesity management. Basing ephedra food supplements on drugs, and ephedra supplement warning on drugs, and promoting drug uses of ephedra supplements clearly establishes that ephedra food supplements are intended to be drugs, but are promoted as nutritional supplements as a ploy to freely violate the FDCA as amended by DSHEA.

Sincerely,